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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,939	02/05/2004	George N. Cox III	4152-1-PUS-7	7950

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EXAMINER

DANG, IAN D

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/773,939

Applicant(s)

COX, GEORGE N.

Examiner

Ian Dang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 24-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 24, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted preceding the first amino acid of the mature IL-11 protein.
- II. Claim 25, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted following the last amino acid of IL-11.
- III. Claims 26 and 27, drawn to a cysteine variant of interleukin-11 wherein the cysteine residue is inserted between at least one pair of two adjacent amino acids located in the region of IL-11 preceding helix A.
- IV. Claims 26 and 28, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in the region of IL-11 following helix D.
- V. Claims 26 and 29, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in the A-B loop of IL-11.
- VI. Claims 26 and 30, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in the B-C loop of interleukin 11.
- VII. Claims 26 and 31, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in the C-D loop of IL-11.
- VIII. Claims 26 and 32, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in at least one region of IL-11 selected from the group consisting of the 1<sup>st</sup> or last 3 residues of helix A.
- IX. Claims 26 and 33, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in at least one region of IL-11 selected from the group consisting of the 1<sup>st</sup> or last 3 residues of helix B.

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- X. Claims 26 and 34, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in at least one region of IL-11 selected from the group consisting of the 1<sup>st</sup> or last 3 residues of helix C.
- XI. Claims 26 and 35, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between at least one pair of two adjacent amino acids located in at least one region of IL-11 selected from the group consisting of the 1<sup>st</sup> or last 3 residues of helix D.
- XII. Claims 26 and 36, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the region preceding helix A and the region consisting of the 1<sup>st</sup> amino acid residues in helix A.
- XIII. Claims 26 and 37, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the region consisting of the last 3 amino acids in helix A.
- XIV. Claims 26 and 38, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the A-B loop and the region consisting of the 1<sup>st</sup> three amino acids in helix B.
- XV. Claims 26 and 39, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the B-C loop and the region consisting of the last three amino acids in helix B.
- XVI. Claims 26 and 40, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the B-C loop and the region consisting of the 1<sup>st</sup> three amino acids in helix C.
- XVII. Claims 26 and 41, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the C-D loop and the region consisting of the last three amino acids in helix C.
- XVIII. Claims 26 and 42, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the C-D loop and the region consisting of the 1<sup>st</sup> three amino acids in helix D.
- XIX. Claims 26 and 43, drawn to a cysteine variant of interleukin-11 wherein a cysteine residue is inserted between the region following the D loop and the region consisting of the last three amino acids in helix D.

For Groups I-XIX above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIX, and election is required for one of

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inventions (A)-(C). The inventions of subgroups (A)-(C) represent the elected invention wherein the claimed protein varies with an inserted cysteine residue is modified with the following:

(A) a cysteine-reactive moiety

(B) a polyethylene glycol

(C) with at least one polyethylene glycol

Therefore, election is required of one Groups I-XIX and an election is also required to one of subgroups (A)-(C) above.

The inventions are distinct, each from the other because the following reasons:

Inventions of groups I-XIX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, each of the subinventions has the same separate utility as the unmodified IL-11. See MPEP § 806.05(d).

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) and have acquired a separate status in the art because of their recognized divergent subject matter and the necessity of non-coextensive non-patent literature searches, restriction for examination purposes as indicated is proper.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Ian Dang  
Patent Examiner  
Art Unit 1647  
August 14, 2006

  
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